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VIA CM/ECF

December 5, 2024

The Honorable Richard G. Andrews
U.S. District Court for the District of Delaware
844 N. King Street
Wilmington, DE 19801

Re: *In re Entresto (Sacubitril/Valsartan) Patent Litigation*
20-md-2930-RGA, 22-1395-RGA

Dear Judge Andrews:

MSN submits this response because Novartis mischaracterizes background facts and completely misstates and misquotes Indian litigation documents as a distraction from its improper confidentially objection to the FDA documents at issue and failure to abide by its agreement with MSN's regulatory counsel to produce those documents with redactions it believed were necessary. We begin with the FDA documents and then turn to the red-herring Indian litigation documents Novartis brings to the Court's attention.

As explained in MSN's letter, MSN learned of two internal FDA documents that relate to FDA's analysis and findings with respect to the solid state form of MSN's sacubitril/valsartan API (i.e., whether MSN's API is a crystalline complex or mixture). MSN's regulatory counsel had several meet-and-confers and email exchanges with Novartis's regulatory counsel about access to these documents. Those communications began several weeks before the pre-trial conference so that there would be enough time to consider them for inclusion on the exhibit list and potential use at trial. DOJ said the FDA had no objection and deferred to the parties. A week later, Novartis's counsel responded and, following continued email exchanges, the parties actually reached agreement on a mutual exchange of documents. MSN's position was that the two documents it sought, which were from the internal FDA record for MSN's *own* ANDA, did not contain any Novartis confidential information, but Novartis disagreed. Novartis also asked MSN to allow Novartis access to a list of documents from *both* Novartis's NDA record and MSN's ANDA record, and proposed that the parties exchange their respective documents with redactions. *See* Ex. D at pp. 6-8. With the parties' agreement in place, and after a follow-up email from MSN's counsel, Novartis's counsel stated that they "could have the redacted copies ready by Monday [December 2] and would propose to do the mutual exchange then, given the holiday." *Id*. at p. 5. Continued emails followed where Novartis's counsel assured MSN's counsel that the exchange of documents would occur and that they were "working in good faith to finish the redactions." *Id*. at p. 3. When no exchange occurred as agreed to, and with its understanding that the two FDA

documents relevant to this case contain only MSN confidential information, MSN sought Court intervention. MSN does not seek any Novartis confidential information from this FDA record, and will accept redacted versions of the two requested documents to the extent Novartis contends they contain any such confidential information.

Novartis, however, attempts to muddy the waters by raising arguments that have nothing to do with these FDA documents, and it leaves facts unsaid in an apparent attempt to confuse the Court. The Indian litigation exists because Novartis is alleging that MSN's Indian sacubitril-valsartan product infringes a Novartis Indian patent, IN 414518, because it contains a complex. *See* Ex. G at pp. 13 and 29. Novartis fails to mention that it accused MSN of infringement because it believed MSN's Indian product contains the Form S *complex*. But further, Novartis does not tell the Court that MSN has *two different products* under *two different licenses* for sale in the Indian market. One product contains Form S, and a second different product contains a physical mixture of sacubitril and valsartan. In Exhibit E to its letter, Novartis did not include page 5, where MSN's Indian counsel explains that MSN had *not* re-launched its Form S product in India and that "[t]he product on the [Indian] market is not Form S—but a physical mixture of Valsartan and sacubitril." *See* Ex. H at pp. 5-6 (complete version of Plaintiff's Exhibit E). Put another way, the Indian litigation involves a different product and a different foreign patent.

Faced with unfounded allegations that MSN infringes Novartis's Indian patent covering an API complex, MSN prepared two reports disclosing a scientific comparison between (1) the Form-A complex disclosed in Novartis's Indian patent and MSN's Indian formulation with a physical mixture API, and (2) the Form-A complex disclosed in Novartis's Indian patent and a formulation containing Form S. *Compare* Ex. F at 55 ("We have been given the mandate to conduct tests and demonstrate whether the current [mixture] product of MSN is the same as or different from that claimed by [Indian patent] IN414518.") *with* Ex. F at 68 ("We have been given the mandate to conduct tests and demonstrate whether the pharmaceutical product of MSN containing Form-S is the same as or different from that described and claimed by [Indian patent] IN414518"). At no point was there ever a conclusion in those reports that Form-S is a physical mixture. Instead, both reports concluded that the tested products were distinct from Novartis's Form A. *See* Ex. F at 67 ("Polymorphic form Form-A prepared in-house can be clearly distinguished from MSN's [Indian-market] tablets, which contains Sacubitril Sodium and Valsartan Disodium as individual drug substances respectively.") and Ex. F 73 ("Polymorphic form Form-A prepared in-house can be clearly distinguished from MSN's tablets, which contains drug substance Form-S of Sacubitril and Valsartan.") (emphases added).

MSN, however, does not deny that MSN's outside Indian counsel made two uncorroborated statements in the Indian legal filings that MSN's Form-S is a physical mixture. But MSN's outside Indian counsel made those statements in error, as can be seen from the statements in page 5 of Exhibit E that Novartis did not include in its letter to the Court and the test data. Again,

the scientific data discussed above never reached the conclusion that Form-S is a mixture; there was only a comparison between (1) Novartis's Form-A complex and MSN's Indian tablet with a physical mixture API, and (2) Novartis's Form A complex and a Form S Tablet. And the context of Indian counsel's statements make clear that MSN was comparing Form S to Form A. *See, e.g.*, Ex. E at 4 ("[I]t is clearly demonstrated beyond the doubt by Mrs. Padmaja's report submitted by defendant in this court that the supramolecular complex of suit patent [Form A] and the defendant's Form-S are different in X-ray diffraction pattern."). The scientific comparisons to Form A and the context of counsel's statements reveal that those statements were mistaken and attorney error. To that end, MSN has identified Dr. Kondal Reddy Bairy as a rebuttal witness to testify about the facts underlying the Indian litigation, the testing that was conducted against Form A and the mistaken statements made by MSN's Indian counsel, should Novartis attempt to muddle the issues.

In short, Novartis omitted the fact that in India it is arguing that MSN's Form S is a complex that infringes its Indian patent (*see* Ex. G at pp. 13 and 29), while in this U.S. litigation, Novartis claims that Form S is a physical mixture. Novartis also failed to include portions of one of its exhibits that completely contradict its assertion that MSN has somehow admitted Form S is a mixture. And MSN's tests concern comparisons to Form A. These contradictory assertions and omissions make clear that Novartis is attempting to argue whatever is convenient rather than what is true.

It is also clear that Novartis is using MSN's request for relevant and potentially damaging FDA documents in an effort to handcuff MSN and prevent it from presenting evidence demonstrating that MSN's Form S is a complex, not a mixture. Novartis hopes to somehow use the Indian documents during the upcoming trial while at the same time deny MSN the ability to offer potentially relevant FDA evidence rebutting Novartis's assertion on that same issue, suggesting that Novartis is prejudiced and the FDA government records are hearsay. Novartis cannot have it both ways. It is MSN who will be prejudiced on this issue, and this is why MSN had no choice but to raise the relevant FDA documents now with the Court.

With the trial approaching and the impending date for adding documents to the exhibit list, and Novartis's dallying with the agreed-upon exchange, and starting to believe that Novartis was backing-out of the parties' agreement, MSN's counsel had no choice but to file its letter requesting production of the two FDA documents it sought in the exchange. The objections Novartis now raises in its letter are baseless. Novartis should be held to the agreement it reached with MSN and produce the two FDA documents immediately. Indeed, MSN had prepared the redacted documents for production and was ready to exchange them with Novartis. To the extent Novartis continues to believe that the two documents MSN has sought contain Novartis's confidential information, it can make the redactions it deems are appropriate. But Novartis's delay and reneging of the parties' agreement should be rejected.

We are available at the convenience of the Court should Your Honor have any questions regarding the foregoing.

Respectfully,

/s/ Richard C. Weinblatt

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MSN Pharmaceuticals Inc.,
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MSN Life Sciences Private Limited

cc: All Registered Counsel (via CM/ECF)